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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/848,107 | 05/03/2001 | Egon Persson | 6176.200-US | 7628 |

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| EXAMINER | |
|---|---|
| SNEDDEN, SHERIDAN | |
| ART UNIT | PAPER NUMBER |
| 1653 | 7 |

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/848,107 | PERSSON ET AL. | |
| | Examiner | Art Unit | |
| | Sheridan K Snedden | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *14-23 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13 and 24-28, drawn to a variant Factor VII polypeptide, classified in class 530, subclass 350.

II. Claims 14-18 and 21, drawn to nucleic acid, vector, host cell and method of making protein, classified in class 435, subclass 69.6.

III. Claim 19, drawn to a transgenic animal, classified in class 800, subclass 8.

IV. Claim 20, drawn to a transgenic plant, classified in class 800, subclass 295.

V. Claim 22, drawn to a method of making protein from a transgenic animal, classified in class 800, subclass 4.

VI. Claim 23, drawn to a method of making protein from a transgenic plant, classified in class 800, subclass 288.

VII. Claim 29, drawn to a method of treating bleeding disorders, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of invention II are related to the protein of invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the claims of invention II. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by

synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay. Thus, they can be unconnected in use and operation.

Inventions I and III-IV are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case, the product can be made using materially different apparatus, such as any one of the inventions II-IV.

Inventions I and V-VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein of invention I can be made in a materially different process such as in a method of chemical synthesis.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of invention I can be used in a materially different process such as generating antibodies, for example.

Inventions II and III-IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the DNA of invention II can be used to make materially different products, such as either products of inventions II and IV.

Invention II is related to inventions V and VI as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA of invention II can be used in materially different processes, such as in a detection process or in a process to make protein.

The product of inventions II is not used in the method of invention V-VII. Therefore, invention II is patentably distinct from inventions V-VII.

The products of inventions III and IV are related in that they contain the same foreign DNA. However, as the products can be used in materially different processes, such as in the use in the materially different processes of making a protein, invention V and VI for example, the products are patentably distinct.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case, the product of invention III can be used in a materially different process, such as in a method of making antibody.

The product of inventions III is not used in the methods of invention VI-VII. Therefore, invention III is patentably distinct from inventions VI-VII.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of invention IV can be used in a materially different process, such as in a method of making nucleic acid.

The product of inventions IV is not used in the methods of invention V and VII. Therefore, invention IV is patentably distinct from inventions V and VII.

The methods of inventions V-VII require different products and steps and have different endpoints. Therefore, inventions V-VII are patentably distinct.

3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VII, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Reza Green on July 12, 2003 a provisional election was made with traverse to prosecute the invention of I, claims 1-13 and 24-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-23 and 29

are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 and 24-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-13 and 24-28 are indefinite as glycine residue occupies position 305 of SEQ ID NO: 1 as it appears in the sequence listing (paper copy and CRF), not a leucine as recited in the claim. Likewise, amino acids of positions 274, 306 and 309 as viewed in the sequence listing do not correlate with the recitation in the claims.

### *Double Patenting*

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-6, 8-11, 13 and 24-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 12-16, 18-20, 34, 35, 40 and 55-56 of copending Application No. 10/255,032. Although the conflicting claims are not identical, they are not patentably distinct from each other because scope of the claims are directed to identical subject matter.

For instance, claim 1 of Application No. 10/255,032 recites a variant Factor VII peptide that comprises the Leu 305 substitution (regarding claim 1).

Claim 34 specifies the substitution of Leu 305 with either Val, Ile, or Tyr (regarding claim 2).

Claims 12-16 and 18-20 (regarding pending claims 3-6 and 8-9) are directed to substitutions of positions 290-304 (specifically, position 304 is substituted with Tyr, Phe, Leu or Met), substitutions of positions 306-312 (specifically, positions 306 is substituted with Asp or Asn, and position 309 is substituted with Ser or Thr) and substitutions of position 274 (substituted with Met, Leu, Lys, or Arg).

Claim 40 recites an activity ratio of at least 2.0 (regarding claims 10 –11 and 13).

Claims 55 and 56 recite a pharmaceutical composition of the above peptide (regarding claims 24-28).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Applicant may overcome this rejection by amending or canceling the conflicting claims in the current application or copending Application No. 10/255,032.

8. Claims 1-2 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 6 and 7 of copending Application No. 10/109,498. Although the conflicting claims are not identical, they are not patentably distinct from each other because scope of the claims are directed to identical subject matter. For instance, claims 1 and 7 of Application No. 10/109,498 recites a variant Factor VII peptide with at least one amino acid substitution. Claim 5 and 6 teach the substution of Leu 305 with a Valine residue (regarding claims 1 and 2).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Applicant may overcome this rejection by amending or canceling the conflicting claims in the current application or copending Application No. 10/109,498.

***Conclusion***

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
July 17, 2003

SKS

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER